CorDx

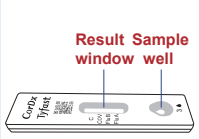
Tyfast Flu A/B & COVID-19 Multiplex Rapid Test

QUICK REFERENCE GUIDE

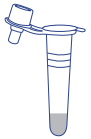
For use under Emergency Use Authorization (EUA) only.
For *in vitro* diagnostic use.
For use with anterior nasal swab specimens.
Store the kit at 36~86°F/2~30°C.
Bring the kit to room temperature (59~86°F/15~30°C) before the test.

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate results.
Refer to the Instructions for Use (IFU) for more complete information.

KIT CONTENTS

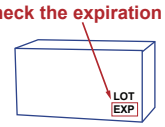


Test cassette


Tube with sample processing solution


QRG & IFU


Swab



TEST PROCEDURES

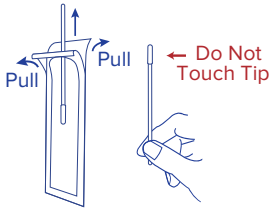
- Only the components provided in the test kit should be used.
- Transport media should not be used. Use of viral transport media with this test may result in inaccurate results.
- It is recommended to use the test kit immediately after opening. The unsealed cassette is valid for 1 hour. Once the sample has been collected, it should be processed within 1 hour.

PREPARING FOR THE TEST

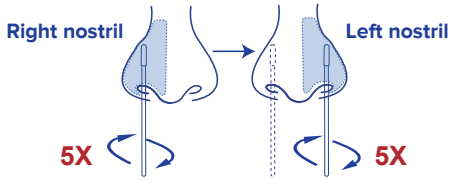
- Read all the instructions before you start the test. Failure to follow the instructions may result in inaccurate test results.
- **Check the test's expiration date (EXP).**
  Do not use an expired test.
- Use a flat level surface (such as a table or countertop) for testing.
- Use a timer during the test.
- Make sure you have all the test components before you begin.
- Bring test kit to room temperature (59~86°F /15~30°C).
- Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

PERFORMING THE TEST

1.
Remove the swab from the pouch.
Note: Be careful not to touch the swab tip (soft end) with hand.



2.
Insert the entire soft end of the swab into the nostril no more than 3/4 of an inch (1.5 cm). Firmly and slowly rotate the swab 5 times, brushing against the inside walls of the nostril to ensure both mucus and cells are collected.
- Do not push the swab further if you meet resistance.
- For young children do not insert more than **1/2** inch.

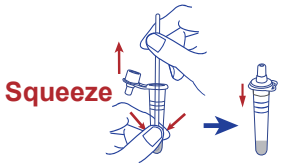


Using the **same swab**, repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils.

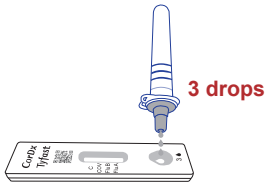
STOP **Did you swab BOTH nostrils?**
Inaccurate test results may occur if the nasal sample is not properly collected.

3.
Insert the swab into the tube until it touches the bottom.
Rotate the swab at least 10 times while pressing the swab head against the bottom and side of the tube.

4.
Remove the swab while squeezing the sides of the tube.
Attach the dropper tip firmly onto the tube.

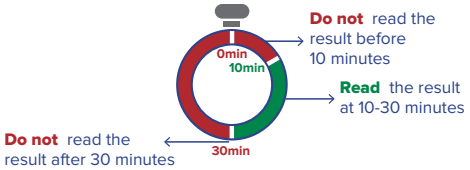


5.
Slowly squeeze the tube and dispense 3 drops of solution into the sample well.



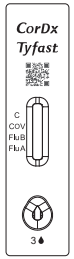
Note: Invalid results can occur if less than 3 drops are added to the Sample Well.

6.
Read the result after 10 minutes but before 30 minutes.



Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

INTERPRETING RESULTS



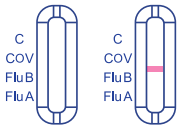
C = Control line
COV = COVID-19 line
Flu B = Influenza B line
Flu A = Influenza A line

Look for lines next to C, COV, Flu B, and Flu A.

FOR EASE OF USE, HOLD TEST CASSETTE NEXT TO THE IMAGES BELOW

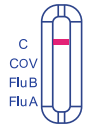
INVALID RESULTS

If the control line (C) is not visible the test is **invalid**, even if any test line is visible. Re-test with a new swab and new test device.



NEGATIVE RESULTS

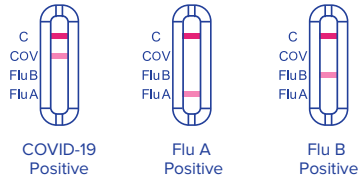
If the control line (C) is visible, but no other lines appear, the test is **negative**.



POSITIVE RESULTS

If the Control line (C) is visible and one or more lines appear(s) for any of the viruses, the test is **positve** for that or those viruses.

NOTE: Multiple lines may appear. The test is positive for all the tests at which a test line appears. Any red line, no matter how faint, should be considered an Indication of a positive result.

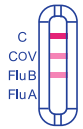


COVID-19 Positive

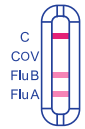
Flu A Positive

Flu B Positive

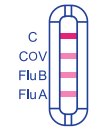
Flu A & COVID-19 Positive



Flu B & COVID-19 Positive



Flu A & Flu B Positive



Flu A & Flu B & COVID-19 Positive

It is possible to have more than one positive test line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one positive test line is observed, retest with a new patient sample and test kit. Repeatable "dual positive" results should be confirmed by an FDA-cleared molecular assay before reporting results.

SERIAL TESTING

Repeat Testing is needed for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2.

Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing**	**Day 2 (Second Test)**	**Interpretation**
SARS-CoV-2 (+) Influenza A and/or B (-)	NO	Not needed	Positive for COVID-19 Presumptive negative for Influenza
SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (-)	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Postive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B

EXTERNAL QUALITY CONTROL PROCEDURE

To perform a positive or negative control test, complete the steps in the TEST PROCEDURES section, treating the control swab in the same manner as a patient swab.

Minimally, CorDx recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

WARNINGS AND PRECAUTIONS

- Do not use the test kit after its expiration date.
- Do not reuse the test cassette, processing solution, or swab.
- Failure to follow the test procedures may adversely affect test performance and/or invalidate the test result.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- This test may only be used in symptomatic individuals.

EUA - WARNINGS AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, and influenza A and B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

INTENDED USE

Please see the Instructions for Use for the full intended use.

The CorDx Tyfast Flu A/B & COVID-19 Multiplex Rapid Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact CorDx Technical Services at **Support@CorDx.com** or contact **858-999-1582**.

CorDx

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